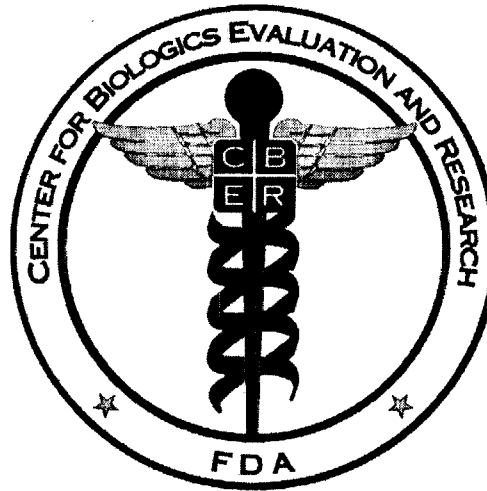


# **I. STRATEGIES FOR INCREASING THE BLOOD SUPPLY: INFORMATIONAL**

**Captain Mary Gustafson**  
**Director, Division of Blood Applications, OBRR, CBER, FDA**

64<sup>th</sup> Meeting  
September 16, 1999  
Bethesda Ramada Inn  
8400 Wisconsin Avenue  
Bethesda, MD



currently **PHS Task Group**  
**Recommendations for**  
**Increasing the Blood Supply**

**Mary Gustafson**

**OBRR, CBER, FDA**

**BPAC, September 16, 1999**



# PHS Task Group Participants

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Kenneth Clark	CDC	Jay Epstein	FDA
Teresa Finlayson	CDC	Mary Gustafson	FDA
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# One Time Industry Participants

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Brian McDonough	ARC
Alan Williams	ARC
Marian Sullivan	NBDRC



# **PHS Task Group Recommendation**

## **Monitor the Blood Supply**

**Short-term: Fund ongoing NBDRC survey efforts**

**Long-term: Establish monitoring as a program under PHS oversight**

# **PHS Task Group Recommendation Remove Restrictions to Safe Donation**

**Short-term:** Allow Hemochromatosis patient donations (case-by-case)

**Long-term:** Remove financial incentives/Hemochromatosis  
Simplify donor re-entry algorithms  
Revise MSM deferral  
Study Anti-HBc positive donors



# **PHS Task Group Recommendation**

## **Address Economic Issues Facing the Blood Industry**

**Short-term:**      **Provide public forum for  
discussion**

**Long-term:**      **Review government policies  
affecting reimbursement**

# **PHS Task Group Recommendation Encourage More Donations by Eligible Donors**

**Short-term:      Encourage/support industry  
media outreach**

**Long-term:      Support research to increase  
donations  
Encourage childhood education  
initiatives**





# **PHS Task Group Recommendation**

## **Improve Donor Relations as Part of Recruitment and Retention**

**Short-term:        Co-sponsor public workshop**

**Long-term:        Simplify donor questionnaire  
Support computer-assisted  
questionnaire  
Support customer service  
research**



# STRATEGIES FOR INCREASING THE U. S. BLOOD SUPPLY

## I. SUMMARY

At the request of the Assistant Secretary for Health and Surgeon General, David Satcher, M.D., Ph.D., who serves as the Blood Safety Director, the Interagency Working Group on Blood Safety and Availability convened an *ad hoc* task group representing Public Health Service (PHS) agencies, Department of Defense, and selected members of the Food and Drug Administration's (FDA) Blood Products Advisory Committee (BPAC) to advise the PHS Blood Safety Committee on national strategies that may be undertaken to increase the blood supply. The group met by teleconference five times (June 24, 28 and 29 and August 4 and 9, 1999). The group recognized the expertise, experience and insight of the blood industry in identifying problems in the supply and demand for blood. Therefore, representatives of the blood industry were invited on a one-time basis to provide input and comment.

A variety of problems contributing to blood shortages were identified. The problems include the low numbers of people who donate blood on a routine basis, the lack of a national monitoring system for blood collection and usage, and restrictions on donations from some potential donors that may not be necessary to protect the public health. The group recognized that not all problems can be readily solved but have identified some strategies for approaching solutions that can be achieved on a short-term basis. The Department of Health and Human Services (DHHS) should demonstrate leadership in fostering cooperative efforts to maintain adequate supplies of blood across the nation.

Strategies to increase the blood supply will require cooperation between the government and the industry. Possible short-term strategies may include participating in a possible industry sponsored media outreach campaign to encourage blood donations; co-sponsoring a public workshop to help better define the problems and share ideas for solutions; and providing public support for the current monitoring effort of the National Blood Data Resource Center. Other strategies will take a longer time to plan, develop, implement and evaluate. The longer term efforts may include additional donor outreach activities, including educational efforts and customer relations improvements; removal of restrictions on donation from donors who are considered safe but currently deferred from donation; additional blood usage monitoring; and development of therapeutic alternatives to blood.

## II. BACKGROUND

Transfusion of allogeneic blood and blood products is one of the most important medical interventions used to treat patients facing acute, life-threatening situations such as trauma, major surgery and chemotherapy or who require chronic blood component replacement. The United States program to provide patients with these critical transfusion products is based almost entirely on individual volunteerism. Potential blood donors most often are made aware of the need for blood donation through community outreach by local blood banks. In spite of the urgent need for this resource, safety considerations prevent some potential donors' blood from being used. To maintain the safety of this important resource and the health of blood donors, blood collection centers utilize criteria for the selection of donors and perform laboratory testing on donor blood samples (including various tests for infectious diseases). Recent estimates have suggested that the rate of blood donations may not be sufficient to keep pace with an increasing demand.<sup>1</sup> This disparity may be further intensified with additional deferrals that are to be recommended as a precaution against possible transmission of new variant Cruetzfeldt-Jakob Disease (nvCJD).

NvCJD was first recognized in 1996 in the United Kingdom (U.K.).<sup>2</sup> Laboratory and epidemiologic studies have linked nvCJD to an outbreak of bovine spongiform encephalopathy (BSE) in the U.K.<sup>3,4</sup> BSE infection in cattle appeared in the U.K. in 1980, peaked in 1992, and fell to low levels by 1996.<sup>5</sup> At meetings in December 18, 1998, and June 2, 1999, FDA's Transmissible Spongiform Encephalopathies Advisory Committee (TSEAC) recommended that, until more is known about the extent of the epidemic and transmissibility of nvCJD by blood, donors should be deferred from donating blood if they have resided in the U.K. during the BSE outbreak.

At two recent public meetings [6/2/99 TSEAC and 4/29/99 PHS Advisory Committee on Blood Safety and Availability (ACBSA)], Ms. Marian Sullivan, Executive Director, National Blood Data Resource Center (NBDRC), reported information from a 1998 comprehensive survey of U. S. blood collection facilities and transfusion services. These data were compared with data collected in a 1994 survey of the blood supply. The NBDRC is an independent, not-for-profit corporation, conceived and funded by the American Association of Blood Banks (AABB). Some relevant information from the survey included:

1. There were 11.7 million allogeneic blood donations in 1997, a 0.3% decline from 1994.
2. Total whole blood collections (allogeneic, autologous and directed) showed a 5.3% decline over the same period because of large decreases in autologous and directed donations (autologous decreased by 36.5%; directed by 38.6%).
3. Blood utilization increased about 1% each year over this time period.

4. Preliminary linear extrapolation of the data suggested that demand will exceed supply sometime in the year 2000.

Additional presentations at the April 1999 ACBSA included data from the Retrovirus Epidemiology Donor Study (REDS). Dr. George Schreiber, Westat, Inc., who analyzed data collected as part of REDS, noted that although almost half of the U.S. population has donated blood, only about 5% donate in any given year, the majority of them only once. Dr. Alan Williams, American Red Cross (ARC), discussed the industry's use of incentives and their effect on blood donation noting that incentives to donate are widely used and increasingly so used. Other representatives of the blood industry also commented on possible mechanisms to increase supply including: reducing the length of donor questionnaires, developing a defined, maybe even paid, donor pool, and reimbursing for blood transfusions at higher costs. The effects of cost and competition also were discussed during that session, and it was observed that the financial limitations of blood collection organizations tend to restrict donor recruitment efforts.<sup>1</sup>

On June 8, 1999, the Blood Safety Committee of the PHS endorsed the recommendations of the TSEAC regarding deferral of donors for exposure in the U.K. The Blood Safety Committee evaluated the available information and concluded that potential blood donors who had traveled to or resided in the U.K. for six months or more, cumulatively, from January 1, 1980 to December 31, 1996 should be indefinitely deferred. It has been estimated that this policy will decrease national blood donations by approximately 2.2% although the losses may be greater in some areas. The decision of the Blood Safety Committee was announced publicly at FDA's BPAC on June 17, 1999.<sup>6</sup> Recognizing that this decision will likely reduce the U. S. blood supply, the Assistant Secretary for Health and Surgeon General, Dr. David Satcher, directed the PHS Interagency Working Group on Blood Safety and Availability to develop a report on strategies to monitor and increase the U. S. blood supply.

An *ad hoc* subgroup comprised of representatives from FDA, the Centers for Disease and Prevention (CDC), the National Institutes of Health, National Heart, Lung and Blood Institute (NHLBI), the Department of Defense, and selected members of the BPAC was asked to develop these strategies. The group met by teleconference five times between June 24 and August 9, 1999, to propose and discuss various methods that might be applied to increase the national blood supply. In addition, representatives of the blood industry were invited on a one-time basis to discuss blood donor recruitment and retention issues. The industry representatives were from the ARC, America's Blood Centers (ABC), the NBDRC, and the AABB. (See Appendix A for task group members and industry participants.)

### **III. ISSUES and RECOMMENDATIONS**

Any national program undertaken by the blood industry to increase the blood supply deserves the leadership and support of the DHHS. The task group recognized that the blood collection industry has excellent physicians, scientists, and other professionals, including skilled donor recruiters. It is their knowledge and experience that will provide an important element of any national initiative to increase the blood supply. Successful implementation of any of the following approaches will require cooperation and coordination, both within the blood industry and with the PHS agencies.

It was the consensus of the task group that the use of unpaid donors is an important factor in the U. S. blood supply and has contributed fundamentally to the high level of safety that characterizes our blood products. Therefore, although the group acknowledged some successes in the use of paid donors for allogeneic transfusions, the proposed strategies presented are restricted to the recruitment of and collection from volunteer (unpaid) blood donors.<sup>7</sup> The group also concurred that all strategies should be initiated with a mechanism for prospective data collection so that effectiveness can be evaluated. The task group's specific recommendations are presented below (and presented in bulleted format in Appendix B):

#### **A. Monitor the Blood Supply**

Reliable, timely data on national and regional blood supply (collection) vis-à-vis blood use (transfusion) are unavailable. Although periodic retrospective surveys have documented collection and usage trends for specific time periods and seasonal variability is well known, there are no reliable national instruments for anticipating shortages with sufficient lead time to accomplish increased donor recruitment or deliberate redistribution of existing supplies.<sup>1,9,10,11,12,13</sup> In the past this effort has not been funded adequately by the private sector. It is essential that both industry and the PHS have timely access to the data to facilitate planning. With this goal, it is recommended that under interagency guidance an appropriate agency within PHS should arrange for ongoing, proactive monitoring of the nation's blood supply. The resulting information would be used by government and blood centers to forecast or rapidly identify shortages and implement timely remedies.

In the short-term, it seems most reasonable for the PHS to support the current, on-going monitoring efforts of the NBDRC. The task group was advised by Ms. Sullivan that it is the intent of the NBDRC to continue biennial surveys as long as the effort is funded. It was noted

that the surveys conducted by NBDRC are designed for data collection compatibility with previously published surveys by Surgenor and others.<sup>10,11,12,13</sup> In addition to the biennial survey, NBDRC plans a "Quick Count" survey in September 1999 of 150 blood centers to assess availability of transfusion components. This will not include blood usage data from transfusion centers. Data should be analyzed by early November. Other NBDRC planned studies of donor related issues, to commence in the fall of 1999, include an evaluation of the effects of donor incentives and intercenter competition on blood availability. Ms. Sullivan advised the group that it is feasible to set up an information system which would provide up-to-date blood supply information on a routine basis if NBDRC resources could be expanded or externally funded. The working group suggests that funding be provided initially to support monthly surveys of a representative sample of U. S. blood centers and transfusion services. Longer intervals (2-3 months) between surveys would not be sufficient to respond to shortages and may not reflect short term variability supply, e.g., seasonal variability or impact of new donor deferral recommendations.

The NBDRC appears to be the only readily available resource for national data collection at this time. The ARC may have internal data on blood collected in the ARC system, and the AABB operates a National Blood Exchange (NBE) with some data collection capabilities. However, resource sharing requests to the NBE represent a small, defined customer subset that likely would not be representative of the U.S.

It is important to note that currently the NBDRC survey results are available only to its members and only in summary form, with the exception that the NBDRC has made some trend data publicly available.<sup>1,5</sup> In order for the data to be useful to the DHHS, the data would need to be available to the DHHS and the public. Additionally, statistical analysis of the 1998 survey data is limited. Any proposal to fund the NBDRC should include the provision that the surveys be more frequent, subject to more extensive statistical analysis, and the results be made publicly available. While the group viewed support of the on-going effort as the most expeditious approach, it also concluded that the appropriate long-term strategy would be the use of competitive contracting under the direction of PHS to insure adequate monitoring of blood supply availability and use.

## **B. Encourage More Donations by Eligible Donors**

It has been estimated that nearly half the population over age 17 has donated blood at least once. However, only 5% of that population donates blood in a given year. Among active donors

the average number of donations per year has been consistent at 1.5<sup>1,8</sup> These data indicate that the number of eligible donors in the United States is adequate to meet the country's blood needs. The problem of shortages can be solved by encouraging current donors to give blood more frequently and to recruit more eligible donors into the current donor pool. A 15% increase in the average number of donations per donor per year would increase the national supply by 10%.<sup>1</sup> One way to do this would be to get many donors who donate only once or twice a year to give one more time. Beyond that, it is important to encourage a lifetime "habit" of donating by donors who have given once or twice.

One way to encourage donations is to publicize the need for donors. Any publicity campaign should focus on both the retention and increased participation of established repeat donors as well as the recruitment of lapsed and first time donors. An appropriate short-term strategy would be an industry developed, broad based, national media campaign to encourage volunteer blood donation. Where appropriate and strategic, the PHS can encourage such a campaign by the industry. For example, public service announcements by high ranking DHHS officials who would be readily recognized by the public could be provided.

An organized effort should be made to identify successful recruitment models. Various research activities can be supported by PHS agencies to determine why one or two time donors have not continued to donate and to see what measures (e.g., incentives, recognition, convenience) would encourage more frequent donations by current donors who give an average of only 1.5 times per year.

A long-term strategy would be to address the education of children to foster the civic responsibility to be blood donors. Public education starting in elementary school should be useful in developing positive attitudes toward donation.

### **C. Improve Donor Relations As Part of Recruitment and Retention**

The blood supply is dependent upon the volunteerism of Americans; strategies that can be undertaken on a long-term basis should address customer service improvements.. There are competitive pressures to "volunteer" for many charitable causes; and Americans demand better customer service than in the past. Information from an earlier era indicates that few donors (only 2-3%) are lost because of a bad experience at the time of donation.<sup>8,14</sup> However, those studies are over twenty years old. Much has changed in donor interactions with increased donor deferral criteria and increased competition among blood centers for the same donors.<sup>9</sup> There is a need to

determine if current donor practices are effective in encouraging and retaining blood donors recognizing the need to avoid undue incentives to donate.

The issue of donor relations is mostly in the purview of local blood centers, but there may be more similarities than differences from one region to another. The task group identified areas in which government can play a role. In the absence of current published studies, the PHS may co-sponsor with industry, a public workshop for identifying “best practices” for donor recruitment and retention. In addition to sharing “best practices,” the public workshop should address the need and study design of instruments to evaluate donor interactions since much available donor behavioral information is anecdotal.

Longer-term projects that can be undertaken nationally include simplifying the donor questionnaire and/or designing a simplified questionnaire for repeat donors. Davey, and others have reported that donors find the current questionnaire extensive, intrusive, and tedious for repeat donors.<sup>19</sup> The task group felt that the responsibility for this project should be shared within the PHS agencies.

Another longer-term project is the development of the computer-assisted donor history questionnaire. NHLBI is currently supporting a study that is presently in clinical trials phase (See appendix C for NHLBI studies). Once developed, the FDA can encourage its use by accepting the instrument and study data for use by blood centers.

#### **D. Remove Restrictions to Safe Donation**

Some healthy donors are restricted from donation for transfusion by existing government or blood center policies. The PHS should investigate whether all current deferrals are necessary to protect the public health. The country will soon enter a new era of improved infectious disease testing. Currently, most blood centers are testing (under investigational protocols) and anticipate use of, nucleic acid testing (NAT) for HCV. Concurrently, many blood centers are also using (under investigational protocols) NAT for HIV. When new technologies such as NAT are licensed, a review of deferrals should be undertaken in the context of universal application of the technologies. Specific donor deferral issues which deserve review are discussed below:

##### **1. Hemochromatosis**

The PHS should move proactively to determine whether hemochromatosis patients can donate as normal donors. This patient group is very active and would like to be able to donate. Medical data support that hemochromatosis patients are not less safe donors because



of their disease; however, there are questions about the voluntary nature of their donations because people with hemochromatosis require phlebotomy as therapy. The obligate need for phlebotomy introduces an incentive to donate blood for transfusion because most patients are charged for the therapeutic removal of blood. The concern is that a financial incentive to donate at no cost, rather than be phlebotomized therapeutically, might cause the donor to be less truthful about acknowledging risk behaviors. Removing patient cost for therapeutic phlebotomy would alleviate that concern. To accomplish this, the DHHS must identify and remove barriers to providing reimbursement support for all therapeutic phlebotomies.

This action by DHHS can only be effective if changes in blood labeling are made in concert. If subjected to special labeling as presently required by blood regulations, the product probably will not be used. Currently, Title 21, Code of Federal Regulations, Part 640.3(d) requires the disease state to appear on the label of blood obtained therapeutically. FDA must determine if this regulation should be changed to facilitate use of blood from hemochromatosis patients, i.e., to allow blood from hemochromatosis patients undergoing therapeutic phlebotomy to be labeled no differently than blood from volunteer donors. Recent publications suggest that allowing hemochromatosis patients to donate may have a significant positive effect on supply.<sup>15,16</sup>

On the other hand, some estimates show that hemochromatosis patients already donate without revealing their diagnosis with the same frequency as hemochromatosis is detected in the population. If true, no effect would be seen if hemochromatosis patients were officially entered into the donor pool.<sup>17</sup> Prospective studies should be undertaken to evaluate the frequency of donation and the viral marker rates from this population.

## **2. Donor re-entry – history of positive viral markers**

Donor deferral policies are created with redundancies and the goal of preventing unsafe donors from re-entering the donor pool. Donors deferred in the past because of false-positive viral marker testing can be reinstated after additional testing following a defined testing protocol with interpretive algorithm. By their conservative nature, donor re-entry algorithms do not allow reinstatement of a proportion of past donors who are healthy but deferred because of viral marker testing results. FDA should review donor re-entry algorithms used to reinstate donors deferred because of testing to determine if changes can be made.

## **3. History of male / male sex**

Donors are also deferred because of risk history. One risk deferral category is a male having sex with another male, even once, since 1977. If such risk is acknowledged, the donor is permanently deferred. At recent BPAC meetings and a public workshop, FDA has discussed whether the current deferral policy for males who have had sex with other males should be relaxed by some degree.<sup>18</sup> The BPAC made no decision on this issue but encouraged FDA to continue to gather information to address this question. FDA should continue to review this issue and modify the deferral policy, if warranted.

#### **4. Hepatitis B core antibody**

While the above donor issues can be addressed in the relatively near future, other deferral issues may be addressed in the long term. For example, donors who are hepatitis B core antibody (HBcAb) positive are currently deferred from donating transfusable blood components. However, it is possible that this policy would be changed based on adequate scientific data. It was suggested that the HBcAb testing offered only a limited benefit and about 0.5-1.5% of the donors exhibit reactivity. However, data are not available which specifically address the safety of eliminating this test. Also, there are no figures which indicate the number or percent of donors who are eliminated solely because of their HBcAb reactivity, especially after readjustment of the cut-off for the test to improve its specificity. The task group recommends further studies in this area.

#### **E. Address Economic Issues Facing the Blood Industry**

Throughout discussions, the task group and industry participants repeatedly expressed concerns about the economic distress of the blood industry. Reimbursement practices and competitive pressures of health care today make it difficult for blood banks to recover the cost of new innovations, even when such measures are required. These economic limitations are a strong disincentive for change. The task group recognizes that the economic issues associated with changes in the blood supply will be addressed at the August 26-27, 1999, meeting of the ACBSA.

### **IV. CONCLUSION**

As a result of its discussions, the task group recommends that the highest priority actions by the DHHS should be to monitor the blood supply and to encourage increased donations by eligible blood donors. Short-term strategies include government support of an on-going effort to monitor the blood

supply; government cooperation with a yet-to-be-developed industry public relations campaign to encourage blood donations; and cosponsorship of a public workshop to identify “best practices” in donor recruitment and retention. Longer-term strategies include additional donor outreach efforts, including education and customer relations improvements; removing restrictions from donation for safe, but currently, deferred donors; and additional blood supply monitoring. The development of alternatives to blood therapies also may mitigate blood shortages but lies beyond the scope of this report.

The success of any national effort to affect the blood donor supply will depend on improving the bond between the blood industry and the blood donor community. Effective leadership by the government and cooperation of the blood industry are needed to ensure that the American public can depend on a safe and readily available source of blood therapies.

**Appendices:**

A—List of PHS working group members and industry resource participants

B—Bulleted report format

C—NHLBI Planned Studies

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## **Appendix A:**

### **Task Group Members**

Mary Chamberland	Centers for Disease Control and Prevention
Kenneth Clark	Centers for Disease Control and Prevention
Teresa Finlayson	Centers for Disease Control and Prevention
Glen Fitzpatrick	Department of Defense
Lianne Groshel	Department of Defense
Stephen Nightingale	Department of Health and Human Services
Gilliam Conley	Food and Drug Administration
Jay Epstein	Food and Drug Administration
Mary Gustafson	Food and Drug Administration
Richard Lewis	Food and Drug Administration
Barbara Alving	National Heart, Lung and Blood Institute
Paul McCurdy	National Heart, Lung and Blood Institute
George Nemo	National Heart, Lung and Blood Institute
John Boyle	Blood Products Advisory Committee
Marion Koerper	Blood Products Advisory Committee

### **One Time Industry Participants**

Kay Gregory	American Association of Blood Banks
Celso Bianco	America's Blood Centers
Susan Parkinson	America's Blood Centers
Richard Davey	American Red Cross
Brian McDonough	American Red Cross
Alan Williams	American Red Cross
Marian Sullivan	National Blood Data Resource Center

## Appendix B

### INCREASING THE BLOOD SUPPLY

At the request of the PHS Blood Safety Director, a task group representing PHS agencies, Department of Defense, and invited members of FDA's Blood Products Advisory Committee was convened to advise the Blood Safety Committee on strategies to increase the blood supply that may be undertaken, or augmented, as a national effort. The group views cooperation with the blood industry an important component of any national effort. Current problems identified by the group and recommendations follow.

- A. **Problem:** Reliable, timely data on national and regional blood supply vis-à-vis blood use is unavailable. Although periodic retrospective surveys have documented collection and usage trends for specific time periods, and seasonal variability is well known, there are no reliable national instruments for anticipating shortages with sufficient lead time to accomplish increased donor recruitment or deliberate redistribution of existing supplies. In the past this effort has not been funded adequately from the private sector. It is essential that the industry and DHHS have timely access to the data to facilitate planning.
- Solution:** Provide ongoing, proactive monitoring of the nation's blood supply. The resulting information would be used by government and blood centers to forecast or rapidly identify shortages and implement timely remedies.
- Strategies:** Provide government support to monitor the blood supply.  
*Short-term* – Fund ongoing National Blood Data Resource Center survey efforts with statistical support and request for more frequent surveying.  
*Long-term* – Sponsor a competitive contract for monitoring. Establish monitoring of the blood supply as a program under PHS oversight.
- B. **Problem:** Although nearly half the people over age 17 have donated blood at least once, only 5% of that population donates blood in a given year. Among active donors the average number of donations per year has been consistent at 1.5.
- Solution:** Increase the number of donations per year by repeat donors. Encourage lifetime "habit" of donating by donors who have given once or twice. A 15% increase in the average number of donations per donor per year would increase the national supply by 10%. One way to do this would be to get many donors who donate only once (or twice) a year to give one more time.
- Strategies:** Publicize need for donors. Improve both the retention and increased participation of established repeat donors as well as recruitment of lapsed and first time donors.  
*Short-term* – Encourage industry developed media outreach. Support outreach efforts by providing public statements by DHHS officials.  
*Long-term* – Support research on one/two time donors to determine why they have not continued to donate; conduct research on current donors (who give 1.5x/year) to see what (e.g., incentives, recognition, convenience) would encourage more frequent donations. Support childhood education to develop lifelong donation practices; benchmark successful private efforts to determine if national program is possible.

- C. **Problem:** The blood supply is dependent upon the volunteerism of Americans. People are busy; there are competitive pressures to "volunteer" for many charitable causes; Americans demand better customer service than in the past. Davey, and others have reported that donors find the current questionnaire extensive, intrusive, and tedious for repeat donors. However, the impact of current donor disenchantment, if present, is unknown.
- Solution:** Improve donor relations and outreach..
- Strategies:** Much of the solution depends on local efforts. Some strategies mentioned above crosscut (i.e., incentives, recognition and donor convenience). However, there are identified areas in which government can play a role.
- Short-term* – Cosponsor public workshop for identifying "best practices" for donor recruitment and retention.
- Long-term* – Simplify the donor questionnaire and/or design a simplified questionnaire for repeat donors.
- Support the development of computer-assisted donor history questionnaire and encourage its use.
- Support research on effectiveness of customer service improvements.
- D. **Problem:** Some healthy donors are restricted from donation for transfusion by government / blood center policies.
- Solution:** Ease restrictions on some donor deferrals. The impact of universal application of NAT testing should be considered as a basis to relax some deferrals.
- Strategies:** *Short-term* – Allow hemochromatosis patients to donate without prejudicial labeling of the blood component on a case-by-case basis if no financial incentive is present.
- Long-term* – Remove financial incentives for hemochromatosis donation by 3<sup>rd</sup> party/Medicare support of therapeutic phlebotomies.
- Simplify donor re-entry algorithms.
- Revise deferral for males who have had sex with another male to 5 years – or possibly shorter.
- Encourage scientific studies to determine whether Anti-HBc positive donors may safely donate.
- E. **Problem:** The economic and competitive pressures of health care today make it difficult for blood banks to recover the cost of new innovations, even when they are required.
- Solution:** Improve mechanisms by which the free market automatically can fund safety innovations.
- Strategies:** *Short-term* – Provide a public forum for discussion of economic challenges to the blood industry.
- Long-term*—Review government policies which affect reimbursement for blood products.

## **Appendix C – NHLBI planned studies**

### **NHLBI Research Studies on Donor Recruitment, Motivation and Screening**

With demand for blood increasing and supply decreasing, the AABB National Blood Data Resource Center estimates that overall demand will exceed supply in the year 2000. The recent decision of the U.S. Public Health Service to recommend deferral of donors who have visited and/or resided in the United Kingdom for a cumulative period of six months or greater between 1980 and 1996 will likely exacerbate this problem.

Understanding why people donate blood is paramount to insuring the adequacy and safety of the blood supply. The National Heart, Lung, and Blood Institute (NHLBI) through its Retrovirus Epidemiology Donor Study (REDS) plans to conduct a survey of donor motivations. Furthermore, the Institute plans to evaluate the use, effectiveness, and safety of blood donation incentives. A study is also being considered to determine the feasibility of increasing the frequency of donations in repeat blood donors by one donation per year. The Institute is also supporting a study that is evaluating a computer-assisted interactive video donor screening system. Brief descriptions of these studies follow.

#### **1) Evaluation of the Impact of Recruitment Strategies on Blood Donation Behavior**

Extensive literature exists on ways to recruit blood donors. However, few attempts have been made to study the real-time interactions of blood centers with their donors on a large scale, or to conduct controlled experiments to determine the positive and negative impact of specific recruitment programs, especially those offering various forms of incentives. The primary goal of this study is to produce measurable improvement in donor recruitment efficiency as measured by new and repeat donation behaviors in those subgroups, while monitoring any major changes in deferrable risk.

In Phase I of the study, REDS will interact closely with a small group of mobile blood collection units for approximately 6 months. The recruitment strategies used for donors at a sample of these mobile units such as tele-recruiting, direct mailing, and media appeals will be documented and donor responses to these recruitment strategies will be measured. A combination of mail and on-site survey techniques will be used to measure prevalence of deferrable risk and, donor attitudes and responses to recruitment practices.

Based upon data derived from previous REDS Donor Surveys and available data from Phase I, four REDS blood centers will implement and evaluate experimental incentive programs in Phase II of the study. In this phase, specific incentives and promotional strategies such as cholesterol testing, gifts, or time off from work will be provided to the same mobile units, with the goal of measuring the positive and negative impact of these specific interventions. Prevalence of deferrable risk and recruitment efficiency among sites that implemented new incentives programs will then be measured and compared to similar data obtained in Phase I before implementation of the incentives.

The survey instruments for this study are being developed. It is anticipated that the documents will be submitted to the Office of Management and Budget (OMB) in October 1999 and the study initiated in January 2000.

#### **2) Study of Donor Motivations**

Little appears to be known about what motivates some people to become regular blood donors, or why only about 39 percent of first-time donors return. Adequate information pertaining to donor motivation in various ethnic groups is also lacking; data which would be valuable for minority recruitment efforts. With the current difficulties in maintaining an adequate blood supply, it is important to discern the reasons behind people's decisions to donate, so that better recruitment strategies can be formulated.



The REDS group is in the process of developing a donor survey to examine motivational factors. The survey will be conducted at all five REDS blood centers at both fixed and mobile recruitment sites. Donors will be presented with a questionnaire to be completed during the donation process. Previous REDS donor surveys have yielded low response rates from certain groups of donors, such as first timers, minorities, and the young. It is thought that using the approach of surveying donors while they are still at the center will increase response rates for these groups and be of minimal cost.

Approximately 37,000 donors will be surveyed over a 6-month period at the five REDS centers. The survey will be identity-linked to enable follow-up of donors in the REDS donation database. This will permit REDS investigators to compare actual donation behaviors to stated intent. Questions pertaining to motivational factors and demographic data will be collected. Blood centers will also track incentive use and recruitment techniques at both mobile and fixed sites to permit evaluation of the association between actual exposure to incentives and reported donor motivational factors.

The survey document is currently being developed and will be submitted to OMB in October 1999. The study is scheduled to begin January 2000.

### **3) Study to Increase Blood Donations**

The Institute is currently considering initiating a study within its REDS program to increase the frequency of blood donations in repeat blood donors by one donation per year. For many years, data have repeatedly shown that most blood donors give but once a year (50-70%, most recent REDS data). If a second blood donation is given within 1-2 years of the first, the individual is more likely to become a "regular donor," defined as one who gives every 1-2 years for several years. It is hypothesized that arranging for donors who give 1-2 times yearly to donate blood once more per year is feasible and will increase the blood supply and eliminate shortages.

The study would be conducted in two or more REDS blood centers. For a sample of a blood center's fixed and mobile sites, arrangements would be made for each donor, while resting in the canteen after donating, to make an appointment for the next donation (after 3-6 months). A reminder (card and/or call) will be sent before the appointment. Control sites will have no such appointment plans. Endpoints would be the number of donations at the test sites with an appointment system, compared with those sites who use current procedures. A one year trial should be sufficient to determine the feasibility of this approach.

### **4) Computer-assisted Interactive Video Donor Screening**

The Institute is supporting a grant program to develop an interactive, multimedia video blood and plasma donor health history system; and to evaluate its acceptance and feasibility in operational settings. The principal aims of the program are to improve overall operational systems for screening donors and collecting blood and plasma; and to improve the safety of blood and plasma supplies. These aims will be evaluated in two stages. In the initial stage, the interactive video screening software will have no decision logic and the nursing staff will determine donor suitability from the printed output of the screening system. In the final stage, it is planned to integrate the interactive video donor screening system into the data management system of the donor center resulting in a "paperless" health history assessment.



## DEPARTMENT OF HEALTH &amp; HUMAN SERVICES

Food and Drug Administration  
Rockville MD 20857

August 10, 1999

TO: Assistant Secretary for Health and Surgeon General

FROM: Commissioner of Food and Drugs

SUBJECT: Blood Donations by Individuals with Hemochromatosis

This memorandum is in response to your memorandum dated July 21, 1999. You asked FDA and HCFA to identify strategies that would implement the recommendations of the Advisory Committee on Blood Safety and Availability (ACBSA) regarding blood donations by individuals with hemochromatosis.

On April 29, 1999, the ACBSA recommended that the Department of Health and Human Services "create policies that eliminate incentives to seek donation for purposes of phlebotomy" from patients with diagnosed hemochromatosis who require obligate phlebotomy as therapy for their disease. Further, as undue incentives to donate blood for transfusion (rather than being therapeutically phlebotomized) are removed, the Department "should create policies that eliminate barriers to using this resource." On July 15, 1999, Dr. Shalala wrote to Dr. Arthur Caplan, Chairman, ACBSA, informing him that she concurred with the Committee's recommendation regarding blood donations by individuals with hemochromatosis. She also advised that she was directing HCFA and FDA to identify strategies that would implement this recommendation.

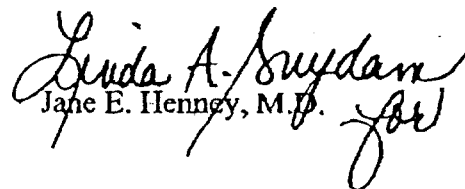
Based on a consideration of this issue within FDA's Office of Blood Research and Review, FDA's Center for Biologics Evaluation and Research (CBER) is committed to the following course of action:

1. For blood establishments that can verify that therapeutic phlebotomy for hemochromatosis is performed at no expense to the patient, FDA will consider case-by-case exemptions to existing regulations. Current regulations require disease-state labeling for units from such collections to be released for transfusion [21 CFR Part 640.3 (d)] and limit the frequency of whole blood collections [21 CFR 640.3(f)]. FDA has the authority to permit exemptions to the blood regulations under the provisions of 21 CFR 640.120.

Page 2 - Dr. Satcher

2. As part of any exemption to blood labeling and/or frequency of collection approved under 21 CFR 640.120, FDA will request that safety data be collected and submitted to the Agency. The data to be submitted will include viral marker rates, incidence of transmissible infections based on rates of seroconversion to viral markers, frequency of post-donation reports of undisclosed risks, and reports of donor and recipient adverse events. These data will be compared with comparable data obtained on the general donor pool.
3. FDA will review any funding plan proposed by HCFA to determine its adequacy in removing the financial incentive for persons with hemochromatosis to donate blood for transfusion. At the April 29 meeting, Dr. Al Grindon, from the Atlanta Region of the American Red Cross, reported that the patient charge for therapeutic phlebotomy ranges from \$52.00 to \$90.00. If less than full reimbursement is established for this procedure, the fact of a remaining charge and inconvenience to patients could leave open the question of an undue donor incentive. The possibility that some patients could remain without coverage by either medicare or private insurance would also need to be considered.
4. Upon a finding that undue financial incentives have been removed for therapeutic phlebotomies of hemochromatosis patients, and with favorable outcomes of surveillance data obtained under 21 CFR 640.120 exemptions to 21 CFR 640.3 (d) and (f), the Agency can propose revisions to the regulations. Such revisions would allow therapeutically obtained blood from hemochromatosis patients to be used without disease-state labeling and allow hemochromatosis patients to be phlebotomized for collection of transfusion products more frequently than once every eight weeks without examination by a physician at each phlebotomy event.

Please let me know if you need any further information on this issue.

  
Jane E. Henney, M.D. JEH



## FDA Response to DHHS Hemochromatosis

Mary Gustafson  
OBRR, CBER, FDA  
BPAC, September 16, 1999



## Hemochromatosis ACBSA Recommendation to DHHS

- ◊ Create policies that eliminate incentives to seek donation for purposes of phlebotomy
- ◊ Create policies that eliminate barriers to using this resource

4/29/99



## Hemochromatosis

- 7/15/99 Dr. Shalala letter to Dr. Caplan concurs with ACBSA recommendation directing HCFA and FDA to identify strategies to implement
- 7/21/99 Dr. Satcher memorandum to HCFA and FDA  
ACTION: Identify strategies to implement ACBSA recommendation



## Hemochromatosis

- 8/10/99 Dr. Henney responded to Dr. Satcher



Strategies developed by  
CBER, Office of Blood  
Research and Review



## Hemochromatosis FDA Course of Action

Consider case-by-case exemptions under 21 CFR 640.120 when phlebotomy performed at no cost to patient

21 CFR 640.3(d) - disease-state labeling

21 CFR 640.3(f) - frequency of whole blood collection



## Hemochromatosis FDA Course of Action

Conditions for exemption -

Collection/submission of safety data

- ◊ viral marker rates
- ◊ seroconversion rates
- ◊ post-donation reports
- ◊ donor/recipient adverse events



## Hemochromatosis FDA Course of Action



Review funding plan  
proposed by HCFA to  
determine adequacy  
in removing financial  
incentive



## Hemochromatosis FDA Course of Action

code of federal  
regulations

Food and Drug
21

After financial incentives  
are removed and with  
favorable outcomes of  
surveillance data, FDA will  
propose revisions to  
regulations

